families of the children to better defend their interest before the health authorities in terms of expenditure (medical or other) for which the part remaining their responsibility is increasing significantly.

Systemic Disorders/Conditions – Clinical Outcomes Studies

PSY1

SEVERE RENAL, HEPATIC AND GASTROINTESTINAL EVENTS ASSOCIATED WITH DEFERASIROX IN PATIENTS WITH TRANSFUSION-DEPENDENT ANEMIA

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OBJECTIVES: Iron chelators (deferasirox or desferrioxamine) are essential to patients who need life-long blood transfusion (e.g. β-Thalassemia). However, in 2010, the US Food and Drug Administration (FDA) had issued a warning on potential adverse events associated with iron chelators, especially deferasirox. The objective of this retrospective cohort study was to compare the risk of renal impairment, hepatic impairment, and gastrointestinal bleeding in patients with transfusion-dependent anemia using deferasirox or desferrioxamine. **METHODS:** Patients with transfusion-dependent anemia (sickle cell disease, β-thalassaemia, myelodysplastic syndrome and aplastic anemia) and were prescribed iron chelators (deferasirox or desferrioxamine) were identified from the 2005−2009 Taiwan's National Health Insurance database. Cox proportional hazards models were used to assess the association between iron chelators and occurrences of adverse events (renal impairment, hepatic impairment, and gastrointestinal bleeding). All models adjusted for age, sex, drug exposure (days), type of transfusion-dependent anemia and medical history. **RESULTS:** Patients were categorized into deferasirox (n=180), desferrioxamine (n=586),and mixed users (n=202), based on the drug they received during the follow-up. The crude rates of adverse events were 4.14, 3.16 and 0.65 per 10,000 person-year in deferasirox, desferrioxamine and mix users, respectively. After adjusting covariates, there was no association between deferasirox and adverse events (hazard ratio [HR]0.84; 95% CI, 0.59–2.00) compared to desferrioxamine users. **CONCLUSIONS:** In this population-based analysis, transfusion-dependant anemia patients using deferasirox and desferrioxamine were at similar risk of adverse events.

PSY2

THE ASSOCIATION BETWEEN THERAPY WITH ANGIOTENSIN-CONVERTING ENZYME INHIBITORS AND HEMOGLOBIN LEVEL

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OBJECTIVES: To assess the hematological effects Angiotensin-converting enzyme (ACE-I) inhibitors and Angiotensin II receptor blockers (ARB) in patients without concomitant renal impairment. **METHODS:** In the present retrospective cohort study we used the Maccabi Healthcare Services' database to identify new users of ACE-I (N=14754) ARB (N=751), or calcium channel blockers (CCB, N=3087) with available hemoglobin (Hb) tests between 2004 and 2009. Excluded were patients purchasing drugs from more than one medication class, diagnosed with renal impairment or cancer. Median Hb levels one year before and after first medication purchase (index date) were calculated and compared according to the proportion of days covered with medication class. **RESULTS:** Persistent use of ACE-I and ARB was associated with a significant decrement in hemoglobin level. Patients at the highest PDC level were at a significantly higher risk of developing anemia among ACEI (OR = 1.59, p<0.001), and ARB (OR = 2.21, p=0.05). The relationship between CCB therapy and Hb decrement was substantially weaker. **CONCLUSIONS:** Hb levels are reduced during the first year of ACE-I or ARB therapy. This association is dose-dependent and is not likely to be caused by artifacts related to patient adherence.

PSY3

OPIOIDS IN NON-MALIGNANT PAIN: ARE THEY EQUIVALENT IN SAFETY PROFILE? A NETWORK META-ANALYSIS

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OBJECTIVES: Severe non-malignant pain affects a large number of patients. Opioids are an important option for analgesia. However, there is relatively little information about the comparative safety of opioids. We sought to compare the safety and tolerability of commonly used opioids in non-malignant pain through network meta-analyses of randomized controlled trials (RCTs). **METHODS:** Medline and Embase were searched from 2000 to 2011 for RCTs comparing commonly used opioids (tramadol, oxycodone, hydrocodone, propoxyphene, codeine) in non-malignant pain. Studies were assessed for inclusion/exclusion based on a prespecified protocol. Two reviewers undertook data extraction independently. Any disagreement was resolved by a third reviewer. A network meta-analysis was used to combine direct and indirect evidence for safety outcomes reported in the trials. Based on the incidence of adverse events (AEs) for each intervention, a probability-based ranking (probability (P) of being worst) was generated using WinBUGS. **RESULTS:** Of the 1156 studies, 5 RCTs enrolling 1399 patients were eligible for inclusion. The most commonly reported AEs were nausea, vomiting, somnolence, dizziness, headache, constipation and dry mouth. Withdrawals due to AEs were most commonly observed with codeine (P=42%) followed by hydrocodone (P=28%), tramadol (P=19%), and oxycodone (P=10%). The probability of occurrence of nausea and somnolence was the highest with codeine. Dizziness was most frequently associated with oxycodone (P= 53%). However, the incidence of dizziness and headache was the lowest with codeine. Tramadol was observed to be associated with the highest (P=40%) incidence of vomiting, while hydrocodone had the lowest incidence (P=15%). **CONCLUSIONS:** Codeine was observed to have the highest incidence of withdrawals due to AEs. It was observed that the probability of occurrence of any particular AE varied across included opioid analgesics. Codeine was observed to have been more frequently associated with nausea/somnolence while tramadol and oxycodone had the highest incidence of vomiting and dizziness respectively.

PSY4

TRENDS IN HYPONATREMIA MANAGEMENT AND ASSOCIATED OUTCOMES IN HOSPITAL SETTINGS: INTERIM RESULTS FROM AN OBSERVATIONAL, PROSPECTIVE, MULTI-CENTER, GLOBAL REGISTRY IN HOSPITALIZED PATIENTS

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OBJECTIVES: Although hyponatremia (HN) is the most common electrolyte abnormality in hospitalized patients, little is known regarding the influence of HN and its management on patient outcomes and healthcare resource usage. The HN Registry is a novel prospective effort to document the clinical and healthcare outcomes of HN and its management. Results for the first 25 HN patients enrolled are described here. **METHODS:** After informed consent or waiver, data were extracted from medical charts of enrolled patients. HN was defined as a serum sodium ≤ 130 mmol/L. The pilot data were summarized appropriately by sample size and for categorical data by percentage. Subjects who had HN on admission were categorized as pre-existing HN patients and those who were admitted for another reason and developed HN while in the hospital were categorized as hospital-acquired HN patients. **RESULTS:** Overall, only 20% of the enrolled patients received any pharmacologic management for HN and approximately 44% were discharged with persistent HN (21% of treated vs. 79% of untreated). Among the patients discharged with HN, 55% had a previous episode of HN. In addition, among the patients with previous HN, 46% were discharged with persistent HN. The length of stay for patients with pre-existing HN was 1.3 days longer compared to patients with hospital-acquired HN. These findings will be further evaluated and reported as more data in this large registry study are accumulated. **CONCLUSIONS:** Among hospitalized patients, HN is frequently untreated, and nearly half of patients are discharged without normalization of serum sodium. HN commonly persists through several hospital admissions.

PSY5

AN INVESTIGATION INTO THE RELATIONSHIP BETWEEN OBESITY AND SKIN AND SOFT TISSUE INFECTIONS REQUIRING HOSPITALIZATION

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OBJECTIVES: The United States is experiencing an obesity epidemic with 67% of adults being either overweight or obese. While it is known that excessive weight increases the opportunity for skin infections, this relationship has not been well studied. This study contributes to the knowledge about the relationship between these two conditions. **METHODS:** Using the H-CUP national database for inpatient hospitalizations, this study analyzed the data from hospitals in the Southern states for the number of skin and soft tissue infections in 2003, 2005 and 2007 in adults. The proportion of patients who were also coded as obese in this population was quantified. Two t-tests were performed comparing the average length of stay for patients who were obese and not obese and the average total hospital charges for patients who were obese and not obese. Two linear regressions analyzed the impact of obesity on the cost of health care by using length of stay and total hospital charges as dependent variables. **RESULTS:** The proportion of patients hospitalized for skin and soft tissue infections who were also obese increased from 48.09% in 2003 to 51.7% in 2007. The average length of stay was 7.97 days for non-obese patients verses 4.6 days for patients coded as obese which was statistically significant. The average total hospital charges were $26,653 for non-obese patients compared to $20,876 for obese patients. This was also statistically significant. Surprisingly, the co-morbidity of obesity has a negative predictive value for both hospital length of stay and total hospital charges. **CONCLUSIONS:** It is possible that patients who are obese are being discharged sooner because of differences in severity of infections. More research is needed to determine whether obesity is a causal factor in skin and soft tissue infections and how this is affecting the cost and delivery of health care.

PSY6

TRANSFUSIONAL IRON OVERLOAD (TIO) MONITORING AND TREATMENT: FINDINGS FROM AN ELECTRONIC MEDICAL RECORDS REVIEW STUDY AT THE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE

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OBJECTIVES: We examined proportions of patients: a) monitored for TIO after receiving ≥10, ≥20, and ≥30 units of red blood cells (RBC) and b) receiving iron chelation therapy (ICT). We also examined overall survival (OS) among: a) monitored vs. unmonitored; b) ICT-treated vs. ICT-untreated groups. **METHODS:** Medical records of patients >18 years receiving ≥10 RBC units ≥6 months before data abstraction were identified at the Moffitt Cancer Center and Research Institute (December 2009-June 2010). Observation period spanned from 10th RBC unit to end of follow-up (i.e., death, clinic departure, or end of observation period). TIO moni-